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Medicis Pharmaceutical Corporation  
and Valeant Pharmaceuticals International*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

MEDICIS PHARMACEUTICAL  
CORPORATION and VALEANT  
PHARMACEUTICALS INTERNATIONAL,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.  
and CADILA HEALTHCARE LTD.,

Defendants.

Civil Action No.: \_\_\_\_\_

*Document Electronically Filed*

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Medicis Pharmaceutical Corporation (“Medicis”) and Valeant Pharmaceuticals

International (“Valeant”) (collectively, “Plaintiffs”) by way of Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) and Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (“Cadila”) (collectively, “Zydus” or “Defendants”) allege as follows:

### **THE PARTIES**

1. Plaintiff Medicis is a corporation organized and existing under the laws of Delaware having its principle place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

2. Plaintiff Valeant is a corporation organized and existing under the laws of Delaware having its principle place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Zydus Pharmaceuticals (USA), Inc. (“Zydus USA”) is a corporation organized and existing under the laws of the State of New Jersey, having a principle place of business at 73 Route 31 N., Pennington, New Jersey 08534.

4. Upon information and belief, Defendant Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (“Cadila”) is a corporation organized and existing under the laws of India, having a principle place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

5. Upon information and belief, Zydus USA is wholly owned by Cadila.

### **NATURE OF THE ACTION**

6. This is an action for infringement of United States Patent Nos. 6,765,001 (“the ’001 patent”), 7,220,424 (“the ’424 patent”), 7,794,738 (“the ’738 patent”), and 8,232,264 (“the ’264 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Zydus’s filing of an Abbreviated

New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic fluocinonide topical cream, 0.1% (“Zydus’s generic fluocinonide topical cream”).

### **JURISDICTION AND VENUE**

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, this court has jurisdiction over Zydus USA. Upon information and belief, Zydus USA is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Zydus USA directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Zydus’s generic fluocinonide topical cream. Upon information and belief, Zydus USA’s principle place of business is at 73 Route 31 N., Pennington, New Jersey 08534. Upon information and belief, Zydus USA is registered to do business in New Jersey under entity ID # 0100915422 and purposefully has conducted and continues to conduct business in this judicial district.

9. Upon information and belief, this court has jurisdiction over Cadila. Upon information and belief, Cadila is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Cadila directly, or indirectly through its wholly owned subsidiaries, manufactures, markets, and sells generic drug products, including generic drug products manufactured by Zydus USA, throughout the United States and in this judicial district, and this judicial district is a likely destination for Zydus’s generic fluocinonide topical cream. Upon information and belief, Cadila

purposefully has conducted and continues to conduct business in this judicial district.

10. Upon information and belief, Zydus USA and Cadila operate as a single integrated business. Upon information and belief, Zydus USA and Cadila share at least one corporate officer.

11. Plaintiffs' claim for patent infringement arose when Zydus sent the required notice of its ANDA filing to Plaintiffs' offices in Bridgewater, New Jersey.

12. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

### **THE PATENTS IN SUIT**

13. The U.S. Patent and Trademark Office ("PTO") issued the '001 patent on July 20, 2004. The '001 patent claims, *inter alia*, formulations of fluocinonide. Plaintiffs hold all substantial rights in the '001 patent and have the right to sue for infringement thereof. A copy of the '001 patent is attached hereto as Exhibit A.

14. The PTO issued the '424 patent on May 22, 2007. The '424 patent claims, *inter alia*, methods of delivering corticosteroids formulations to skin, including fluocinonide formulations. Plaintiffs hold all substantial rights in the '424 patent and have the right to sue for infringement thereof. A copy of the '424 patent is attached hereto as Exhibit B.

15. The PTO issued the '738 patent on September 14, 2010. The '738 patent claims, *inter alia*, methods of delivering corticosteroids formulations to skin, including fluocinonide formulations. Plaintiffs hold all substantial rights in the '738 patent and have the right to sue for infringement thereof. A copy of the '738 patent is attached hereto as Exhibit C.

16. The PTO issued the '264 patent on July 31, 2012. The '264 patent claims, *inter alia*, corticosteroids formulations, including fluocinonide formulations. Plaintiffs hold all

substantial rights in the '264 patent and have the right to sue for infringement thereof. A copy of the '264 patent is attached hereto as Exhibit D.

17. Medicis is the holder of New Drug Application ("NDA") No. 21-758 for Vanos<sup>®</sup>, which the FDA approved on February 11, 2005. In conjunction with NDA No. 21-758, the '001, '424, '738, and '264 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

18. Fluocinonide topical cream, 0.1%, is sold in the United States under the trademark Vanos<sup>®</sup>.

### **ZYDUS'S INFRINGING ANDA SUBMISSION**

19. Upon information and belief, Zydus filed or caused to be filed with the FDA ANDA No. 208-989, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

20. Upon information and belief, Zydus's ANDA No. 208-989 seeks FDA approval to sell in the United States Zydus's generic fluocinonide topical cream, intended to be a generic version of Vanos<sup>®</sup>.

21. Medicis received a letter from Zydus dated February 5, 2016, purporting to be a Notice of Certification for ANDA No. 208-989 ("Zydus's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

22. Zydus's notice letter alleges that Zydus has submitted to the FDA ANDA No. 208-989 seeking FDA approval to sell Zydus's generic fluocinonide topical cream, intended to be a generic version of Vanos<sup>®</sup>.

23. Upon information and belief, ANDA No. 208-989 seeks approval of Zydus's generic fluocinonide topical cream that is the same, or substantially the same, as Vanos<sup>®</sup>.

24. Upon information and belief, Zydus's actions relating to ANDA No. 208-989

complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Cadila.

### **COUNT I AGAINST ZYDUS**

#### **Infringement of the '001 Patent under § 271(e)(2)**

25. Paragraphs 1-24 are incorporated herein as set forth above.

26. Under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '001 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-989 seeking approval for the commercial marketing of Zydus's generic fluocinonide topical cream before the expiration date of the '001 patent.

27. Upon information and belief, Zydus's generic fluocinonide topical cream will, if approved and marketed, infringe at least one claim of the '001 patent.

28. Upon information and belief, Zydus will, through the manufacture, use, import, offer for sale, and/or sale of Zydus's generic fluocinonide topical cream, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '001 patent.

### **COUNT II AGAINST ZYDUS**

#### **Declaratory Judgment of Infringement of the '001 Patent**

29. Paragraphs 1-28 are incorporated herein as set forth above.

30. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

31. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

32. Zydus has made, and will continue to make, substantial preparation in the United

States to manufacture, use, offer to sell, sell, and/or import Zydus's generic fluocinonide topical cream before the expiration date of the '001 patent, including Zydus's filing of ANDA No. 208-989.

33. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '001 patent.

34. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will constitute infringement of at least one claim of the '001 patent.

### **COUNT III AGAINST ZYDUS**

#### **Infringement of the '424 Patent under § 271(e)(2)**

35. Paragraphs 1-34 are incorporated herein as set forth above.

36. Under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '424 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-989 seeking approval for the commercial marketing of Zydus's generic fluocinonide topical cream before the expiration date of the '424 patent.

37. Upon information and belief, Zydus's generic fluocinonide topical cream will, if approved and marketed, infringe at least one claim of the '424 patent.

38. Upon information and belief, Zydus will, through the manufacture, use, import, offer for sale, and/or sale of Zydus's generic fluocinonide topical cream, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '424 patent.

### **COUNT IV AGAINST ZYDUS**

#### **Declaratory Judgment of Infringement of the '424 Patent**

39. Paragraphs 1-38 are incorporated herein as set forth above.

40. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

41. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

42. Zydus has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Zydus's generic fluocinonide topical cream before the expiration date of the '424 patent, including Zydus's filing of ANDA No. 208-989.

43. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '424 patent.

44. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will constitute infringement of at least one claim of the '424 patent.

#### **COUNT V AGAINST ZYDUS**

##### **Infringement of the '738 Patent under § 271(e)(2)**

45. Paragraphs 1-44 are incorporated herein as set forth above.

46. Under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '738 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-989 seeking approval for the commercial marketing of Zydus's generic fluocinonide topical cream before the expiration date of the '738 patent.

47. Upon information and belief, Zydus's generic fluocinonide topical cream will, if approved and marketed, infringe at least one claim of the '738 patent.



48. Upon information and belief, Zydus will, through the manufacture, use, import, offer for sale, and/or sale of Zydus's generic fluocinonide topical cream, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '738 patent.

### **COUNT VI AGAINST ZYDUS**

#### **Declaratory Judgment of Infringement of the '738 Patent**

49. Paragraphs 1-48 are incorporated herein as set forth above.

50. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

51. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

52. Zydus has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Zydus's generic fluocinonide topical cream before the expiration date of the '738 patent, including Zydus's filing of ANDA No. 208-989.

53. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '738 patent.

54. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will constitute infringement of at least one claim of the '738 patent.

### **COUNT VII AGAINST ZYDUS**

#### **Infringement of the '264 Patent under § 271(e)(2)**

55. Paragraphs 1-54 are incorporated herein as set forth above.

56. Under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '264 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-989 seeking approval for the commercial marketing of Zydus's generic fluocinonide topical cream before the expiration date of the '264 patent.

57. Upon information and belief, Zydus's generic fluocinonide topical cream will, if approved and marketed, infringe at least one claim of the '264 patent.

58. Upon information and belief, Zydus will, through the manufacture, use, import, offer for sale, and/or sale of Zydus's generic fluocinonide topical cream, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '264 patent.

### **COUNT VIII AGAINST ZYDUS**

#### **Declaratory Judgment of Infringement of the '264 Patent**

59. Paragraphs 1-58 are incorporated herein as set forth above.

60. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

61. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

62. Zydus has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Zydus's generic fluocinonide topical cream before the expiration date of the '264 patent, including Zydus's filing of ANDA No. 208-989.

63. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will directly infringe,

contributorily infringe, and/or induce infringement of at least one claim of the '264 patent.

64. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic fluocinonide topical cream will constitute infringement of at least one claim of the '264 patent.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request that the Court enter judgment in their favor and against Zydus on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '001 patent by submitting or causing to be submitted ANDA No. 208-989 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus's generic fluocinonide topical cream before the expiration of the '001 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '424 patent by submitting or causing to be submitted ANDA No. 208-989 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus's generic fluocinonide topical cream before the expiration of the '424 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '738 patent by submitting or causing to be submitted ANDA No. 208-989 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus's generic fluocinonide topical cream before the expiration of the '738 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '264 patent by submitting or causing to be submitted ANDA No. 208-989 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus's generic fluocinonide topical cream before the expiration of the '264 patent;

5. order that that the effective date of any approval by the FDA of Zydus's generic fluocinonide topical cream be a date that is not earlier than the expiration of the '001, '424, '738, and '264 patents, or such later date as the Court may determine;

6. enjoin Zydus from the commercial manufacture, use, import, offer for sale, and/or sale of Zydus's generic fluocinonide topical cream until expiration of the '001, '424, '738, and '264 patents, or such later date as the Court may determine;

7. enjoin Zydus and all persons acting in concert with Zydus from seeking, obtaining, or maintaining approval of Zydus's ANDA No. 208-989 until expiration of the '001, '424, '738, and '264 patents;

8. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

9. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: March 21, 2016

Respectfully submitted,

s/ William P. Deni, Jr.

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**CERTIFICATION OF NON-ARBITRABILITY**  
**PURSUANT TO LOCAL CIVIL RULE 201.1(d)**

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

Dated: March 21, 2016

s/ William P. Deni, Jr.

William P. Deni, Jr.

Charles H. Chevalier

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